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Re-evaluation Note REV2017-22

Re-evaluation Project Plan for 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin

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Background

In Canada, 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin are under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin are registered as antimicrobial active ingredients used for the preservation of various products such as liquid detergents, soft soaps, room deodorizers, polymer emulsions and water-based gels for household and industrial products. As of 24 May 2017, there are two technical grade products and five end-use products containing these active ingredients registered for use in Canada.

Under the authority of section 16 of the *Pest Control Products Act*, all registrants of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin were notified of the initiation of the re-evaluation. Following this, the registrant of these technical grade active ingredients in Canada indicated their support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline for review, summarizes the anticipated areas of focus for the risk assessments, and lists the data requirements for this re-evaluation.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin is defined as a Category 1, as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin is anticipated to be published for consultation by August 2019. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, occupational exposure, and residential assessments.

Environmental Risk Assessment

Existing assessments with minor updates are considered to be adequate to support the re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin for most review areas.

Value

The value of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin will be considered. The viability of alternatives will be examined for certain uses if risks of concern which require mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrant to provide data for 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin related to toxicology, occupational exposure and environment. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found in the PMRA's Public Registry found online at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html. For a list of data categories that have been requested from the technical registrant, see Appendix I.

Additional Information

The PMRA documents can be found in the Pesticides and Pest Management portion of the Canada.ca website at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
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Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin

I. Toxicology

DACO 4.1	Summary of toxicological studies
DACO 4.2.1	Acute Oral
DACO 4.2.2	Acute Dermal
DACO 4.2.3	Acute Inhalation
DACO 4.2.4	Primary Eye Irritation
DACO 4.2.5	Primary Dermal Irritation
DACO 4.2.9	Other Acute Studies (rat and rabbit)
DACO 4.3.1	Short-term Oral (90-day rodent)
DACO 4.3.4	Short-term Dermal (90-day
DACO 4.5.2	Prenatal Developmental Toxicity (rodent)
DACO 4.5.3	Prenatal Developmental Toxicity (non-rodent)
DACO 4.5.8	Other Genotoxicity Studies (DNA synthesis assay)
DACO 6.4	Other Studies/Data/Reports (absorption/distribution/metabolism and excretion)

II. Occupational Exposure

DACO 5.4	Mixer/Loader/Applicator- Passive Dosimetry Data
DACO 5.5	Mixer/Loader/Applicator-Biological Monitoring Data
DACO 5.6	Post Application - Passive Dosimetry Data
DACO 5.7	Post Application - Biological Monitoring Data
DACO 5.9	Dislogeable Residues (Foliar, Soil and Surface)

III. Environment

DACO 8.2.3.2	Hydrolysis
DACO 8.2.3.3.2	Phototransformation - Water